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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Minneapolis District
240 Hennepin Avenue
Minneapolis MN 55401-1999
Telephone: 612-334-4100

PURGED

May 11, 1998

cc: HFI-35/FOI Staff
DWA

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 98 - 22

Lee L. Krienke
Route 3, Box 229
Sleepy Eye, Minnesota 56085

Dear Mr. Krienke:

An inspection of your medicated feed mill located at Sleepy Eye, MN, on March 26, 1998, by Rick Manthei on behalf of the Food and Drug Administration (FDA) found significant deviations from Current Good Manufacturing Practice (CGMP) regulations for Medicated Feeds [Title 21, Code of Federal Regulations, Part 225 (21 CFR 225)]. Such deviations cause medicated feeds being manufactured at your facility to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (the Act).

Our investigation found the following deviations:

1. For feed requiring an approved Mill License for their manufacture and marketing, at least three representative samples of medicated feed containing each drug or drug combination used in the establishment shall be collected and assayed by approved official methods, at periodic intervals during the calendar year. If a medicated feed contains a combination of drugs, only one of the drugs need be subject to analysis each time, provided the one tested is different from the one(s) previously tested. No analyses were done for feeds containing [redacted] during 1997 [21 CFR 225.58(b)(1)].

2. All equipment, including scales and liquid metering devices, shall be of suitable size, design, construction, precision, and accuracy for its intended purpose. Spring loaded, dial type, hanging scales are of questionable design to assure the necessary precision and accuracy required to weigh drug components [21 CFR 225.30(b)(3)].

3. All scales and metering devices shall be tested for accuracy upon installation and at least once a year thereafter, or more frequently as may be necessary, to insure their accuracy. There is no documentation that the scales have been tested [21 CFR 225.30(b)(4)].

4. The building(s) shall be of suitable construction to minimize access by rodents, birds, insects, and other pests. Numerous mice were observed in the mixing and bag storage area. Cracks and crevices in the floor indicated an unusually high traffic pattern of rodents [21 CFR 225.20(b)(3)].

The above is not intended to be an all-inclusive list of CGMP violations. As a manufacturer of medicated and non-medicated feeds, you are responsible for ensuring that your overall operation and the products you manufacture and distribute are in compliance with the law. Enclosed is a copy of the CGMP regulations that apply to your facility [21 CFR 225.1-120].

You should take prompt action to correct these CGMP violations and you should establish procedures whereby such violations do not recur. Failure to promptly correct these CGMP violations may result in regulatory and/or administrative sanctions. These sanctions include, but are not limited to, seizure, injunction and/or notice of opportunity for a hearing on a proposal to withdraw approval of your mill license under Section 512(m)(4)(B)(ii) of the Act and 21 CFR 514.115(c)(2).

This letter constitutes official notification under the law. Based on the result of the March 26, 1998, inspection, together with the evidence before FDA when the Mill License was approved, the methods used in, or the facilities and controls used for, the manufacture, processing, and packing of medicated feed are inadequate to assure and preserve the identity, strength, quality, and purity of the new animal drugs therein. This letter notifies you of our findings and provides you an opportunity to correct the above deficiencies.

You should notify this office in writing within 15 working days of receipt of this letter of the steps you have taken to bring your firm into compliance with the law. Your response should include an explanation of each step being taken to correct the CGMP violations and prevent their recurrence. If corrective action cannot be completed within 15 working days, state the reason for the delay and the date by which the corrections will be completed. Include copies of any available documentation demonstrating that corrections have been made.

Your reply should be directed to Compliance Officer Robert P. Snell at the address on the letterhead.

Sincerely,

James R. Rahto
Director
Minneapolis District

RPS/ccl

Enclosure: 21 CFR 225.1-120